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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/486,703	06/27/2000	IAN ROSS DOYLE	017227/0157	9876

7590 11/29/2002

STEPHEN A BENT
FOLEY & LARDNER
WASHINGTON HARBOUR
3000 K STREET NW SUITE 500
WASHINGTON, DC 20007-5109

EXAMINER
DUFFY, PATRICIA ANN

ART UNIT	PAPER NUMBER
1645	12

DATE MAILED: 11/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/486,703	Doyle et al
Examiner	**Group Art Unit**
DUFFY	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 9-18-02.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-36 is/are pending in the application.

Of the above claim(s) 13-34 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-12 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claim(s) 1-36 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3+7

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

DETAILED ACTION

1. The response filed 9-18-02 has been entered into the record.

Information Disclosure Statement

2. The information disclosure statements filed 6-6-00 and 10-18-00 have been considered. Signed copies are enclosed.

Election/Restriction

3. Applicant's election with traverse of Group I, claims 1-12 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the Examiner's position in relation to the requirement is in contravention of the terms of the Patent Cooperation Treaty Article 27(1) of the PCT. This is not found persuasive because the examiner is not in fact in contravention, the Examiner has applied PCT Rule 13.1 as it relates to the "special technical feature" of Rule 13.2. The examiner has applied the appropriate PCT rules and explained that the relied upon technical feature is not "special" and therefore unity of invention is lacking. Anticipatory art, necessarily negates unity of invention because the relied upon technical feature does not define a contribution over the prior art. This is the PCT standard that has been correctly applied in this national stage application. Applicant

argues that the National Stage Examiner is therefore necessarily bound by the findings of Unity of Invention of the International Authority. It is noted that no U.S. Examiner is bound by any findings of lack thereof by the International Authority.

The lack of unity requirement is still deemed proper and is therefore made FINAL.

4. Claims 13-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the lack of unity requirement in Paper No. 10.

Claim Rejections - 35 U.S.C. § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of diagnosing lung damage by measuring an increase in pulmonary surfactant A (SP-A) and /or pulmonary surfactant B (SP-B), does not reasonably provide enablement for diagnosing lung damage by measuring decreases in SP=A or SP-B or measuring levels of pulmonary surfactant C (SP-C) or pulmonary surfactant D (SP-D) or decreases in any of SP-A or B. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to a method of diagnosing lung damage in a mammal comprising screening for the modulation of pulmonary surfactant levels in the body fluid of said mammal. The specification specifically teaches that SP-A and SP-B levels increase in plasma with lung damage. The specification fails to teach that any of SP-A or SP-B decrease in any body fluid with lung damage and as such are not enabled for the scope of "modulation" which reads on either an increase or decrease in levels. Furthermore, the specification fails to teach the correlation of SP-C and SP-D with lung damage. The specification does not teach if levels increase or decrease in lung damage. As such, the specification is not enabled for measuring SP-C or SP-D as a diagnostic for lung damage because the specification does not teach the correlation of these markers with lung

disease. The correlation of markers as either increasing or decreasing with a specific disease is the critical inventive concept of the invention, since both SP-C and SP-D were known to the art at the time of this invention. Since this specification does not teach whether these claimed markers increase or decrease in body fluids in a mammal with a lung disease or disorder it is not enabled for such because the person of skill in the art would not know how to interpret the outcome of the assay with respect to lung damage.

In view of a lack of demonstration of a correlation of SP-C and SP-D with lung disease, one skilled in the art would have to determine for themselves the actual correlation, if it indeed exists. As such, the specification is not enabled for these two markers. Further, the specification does not teach a single body fluid wherein the levels of SP-A or SP-B decreases with lung disease and as such is not enabled for "modulation", because the specification fails to set forth even one body fluid where a decrease from normal would be indicative of disease. In view of the foregoing, the specification does not enable the full scope of the claims.

8. Claims 8-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of monitoring the changes in the extent of lung damages by measuring changes in SP-A and or SP-B , does not reasonably provide enablement for measuring changes in SP-C and/or SP-D. The specification does not enable

any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are drawn to a methods of monitoring the changes in the extent of lung damages by screening for modulation of pulmonary surfactant levels in the body fluid of said mammal. The specification specifically teaches that SP-A and SP-B levels increase in plasma with lung damage and decrease with healing. The specification fails to teach the correlation of SP-C and SP-D with lung damage. The specification does not teach if levels increase or decrease in lung damage. As such, the specification is not enabled for measuring SP-C or SP-D as a method for monitoring changes in the extent of lung damage in a mammal because the specification does not teach the correlation of these markers with lung disease and their modulation with respect to changes in the extent of lung damage. The correlation of markers as either increasing or decreasing with a specific disease and the is the critical inventive concept of the invention, since both SP-C and SP-D were known to the art at the time of this invention. Since this specification does not teach whether these claimed markers increase or decrease in body fluids in a mammal with a lung disease or disorder and further do not indicate that they are appropriately modulated with the extent of lung damage, it is not enabled for such because the person of

skill in the art would not know how to interpret the outcome of the assay with respect to extent of lung damage.

In view of a lack of demonstration of a correlation of SP-C and SP-D with lung disease and their modulation with the extent of lung damage, one skilled in the art would have to determine for themselves the actual correlation, if it indeed exists. As such, the specification is not enabled for these two markers. In view of the foregoing, the specification does not enable the full scope of the claims.

9. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are rendered indefinite because it requires a modulation or comparison and the claims do not define what the screened amount is compared to. As such, it is unclear how to interpret the outcome of the assay as increased, decreased or no change. When their is no comparison to a baseline.

Claim Rejections - 35 U.S.C. § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-5, 7-10 and 12 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Honda (Japanese Journal of Thoracic Diseases, 34 Suppl. Abstract only, December 1996; reference A11 on PTOL-1449 of 6-6-00).

Honda teach the measurement of surfactant proteins A and D in the sera of patients with idiopathic interstitial pneumonia by enzyme-linked immunosorbent assay using monoclonal antibodies against human SP-D and SP-A. Honda teaches that SP-D and SP-A increase in the sera from diseased patients. Honda teach that the results suggest that SP-D and Sp-A, which are primarily secreted from alveolar type II cells into the lumen, can enter the blood stream easily do to injury at the alveolar-capillary membrane. Further the serum SP-D and SP-A concentrations appeared to reflect disease activity of IIP (see abstract).

12. Claims 1-5, 7-10 and 12 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Abe et al (Japanese Journal of Thoracic Diseases, 33(11):1219, Abstract Only, November 1995; reference A10 on PTOL-1449 of 6-6-00).

Abe et al teach that the serum levels of SP-A in patients with IIP and that the SPA-levels correlated closely with the clinical course and rose significantly during exacerbations of IIP (see abstract).

13. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ian R. Doyle (Advances in Critical Care Testing, Eds. List, Muller and McQueen, Springer-Verlag Telos, January 1997; reference A17 on PTOL-1449 10-18-00).

Doyle et al teaches the increase in SP-A and SP-B in critically ill patients with respiratory failure (see Results, first page) in plasma (i.e. the instant body fluid). Doyle et al teach that individually, daily changes in lung function (i.e. the instant disease extent) were acutely reflected in concomitant variations in plasma SP-A, SP-B and SP-B/SP-A ratio (see second page first full paragraph and Tables 1 and 2 respectively) and concludes that the levels reflect the severity of lung injury.

As such, Doyle et al anticipates the instantly claimed inventions.

Status of Claims

14. No claims are allowed.

15. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the

notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Monday-Thursday and Saturday from 10:30 AM to 7:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D.
November 26, 2002

Patricia A. Duffy

Patricia A. Duffy, Ph.D.
Primary Examiner
Group 1600